

if outcome scores for the levels are significantly different; (iii) Ascertain whether levels distinguish people of varying clinical profile (injury level and completeness). **METHODS:** A three-phase analytic approach involving quantitative and qualitative methodology was deployed: (a) SCI-FI items were ordered along a continuum of difficulty using IRT, and empirical item maps were generated from calibration study data (N=855); (b) Delphi approach was employed with expert panel (n=6) reviewing item maps and arriving at consensus for cut-off scores for level development; and (c) Developed levels were described and refined for meaningful outcome interpretation. One-way ANOVAs were performed (levels as factor, SCI-FI CAT scores as dependent variable). Chi square analyses were performed to compare actual to expected number of persons at each level for the varied clinical profiles, paraplegia-complete, paraplegia-incomplete, tetraplegia-complete and tetraplegia-incomplete. **RESULTS:** Five levels representing varying range of functional outcomes were identified for all the SCI-FI domains except one having four levels. ANOVA (pair-wise comparisons) results revealed significant score differences across levels. Chi-square tests were significant in the hypothesized direction. **CONCLUSIONS:** Developed levels define patient functional outcomes that provide meaningful interpretation of CAT scores for use in research and patient monitoring.

RESEARCH POSTER PRESENTATIONS – SESSION I

HEALTH CARE USE & POLICY STUDIES

HEALTH CARE USE & POLICY STUDIES – Consumer Role in Health Care

PHP1

EFFECT OF INVOLVEMENT ON INFORMATION PROCESSING FROM OVER-THE-COUNTER DRUG FACTS PANEL

Bhansali AH, Sansgiry SS
University of Houston, Houston, TX, USA

OBJECTIVES: The study objective was to assess the effect of involvement on information processing from over-the-counter (OTC) Drug Facts panel. **METHODS:** In this experimental, cross-sectional study the effect of extrinsic involvement when processing two experimental labels was evaluated. Labels designed based on concepts of chunking, congruency and information placement were compared to the current OTC label. Extrinsic involvement was measured using a previously validated and reliable scale along with information processing variables measured using the OTC-label evaluation process model. The participants were tested for label comprehension, ease of use, attitude towards the label, product evaluation and purchase intention. Data was coded and analyzed using SAS® 9.3 at an a priori significance level of 0.05. MANCOVA, ANCOVA, Dunnett's post-hoc analyses were done to test the study objective. **RESULTS:** Of the 249 survey participants (81.4% response rate) majority were females (55.4%) with a mean age of 36.8 (\pm 9.6) years. Most of them had a college level education (54.2%) and worked in the health care field (61.4%). In general, extrinsic involvement scores were high (3.81 \pm 1.03). MANCOVA indicated a statistically significant effect of involvement between the label types ($p < 0.0001$). ANCOVA and Dunnett's post hoc revealed that the level of involvement for attitude towards the label was significantly higher for Label A with warnings placed after the chunk (Uses, Directions, Other Information) as compared to Label B with warnings placed before the chunk and Label C, the current OTC label ($p < 0.0001$). **CONCLUSIONS:** Consumer involvement plays a significant role in information processing. Consumer attitude towards the label information is affected by their level of involvement. When the consumer is more involved he is more likely to understand the given information and have a favorable attitude towards the product.

PHP2

ICD-10 IMPLEMENTATION IN SAUDI ARABIA: CHALLENGES AND OPPORTUNITIES! E-HEALTH IS TRANSFORMING MEDICAL RECORDS TO HEALTH INFORMATION MANAGEMENT!

Albishi HA
Ministry of Health, RIYADH, Saudi Arabia

OBJECTIVES: ICD-10 is mandated by the World Health Organization (WHO). It codes diseases, signs and symptoms, abnormal findings, complaints, social circumstances, and external causes of injury or diseases. ICD-10 coding is used for measuring the quality, safety and efficacy of care, tracking public health concerns, epidemiological studies, and, improving clinical, financial, and administrative performance. Accurate and precise coding utilizing standardized methodologies on a national scale is both challenging and meticulous process. This paper aims to highlight the implementation challenges of ICD-10 coding in Saudi Arabia from the year (2007) to the year (2014). The main challenges and opportunities observed during the implementation process will be presented. **METHODS:** The methodology of the implementation process of ICD-10 started in 2007, the first step started with signing an agreement between the Saudi Arabia and Australia to obtain a license agreement, the second step was creating a committee to oversee the implementation, and the third step was preparing an implementation guide with the following objectives, to increase the level of awareness to understand the ICD-10 impact, and enable hospitals and software vendors to adopt to the new system. **RESULTS:** ICD-10 implantation faced some challenges, some were coders-related and some were organization-related. Among the most important coders challenges were the lack of ICD-10 training resources, poor English literacy, and significant shortage of coders (7%) and medical records staff (45%). The absence of a clear professional career path for Hospital Information Management (HIM) Specialists and Clinical Coders has played an important role in limiting the coding process in Saudi Arabia. Organization challenges included lack of ICD-10 awareness, poor technical infrastructure, lack of interoperability with legacy and dated Hospital Information Systems, and the lack of a Discharge Abstract Data (DAD) System with defined

minimum data sets. **CONCLUSIONS:** The Saudi National e-health Strategy will leverage the ICD-10 implementation.

PHP3

IS FDA'S BREAKTHROUGH THERAPY DESIGNATION A GAME-CHANGING TREND FOR PATIENTS AND PAYERS?

Aggarwal S, Topaloglu H
Novel Health Strategies, Bethesda, MD, USA

OBJECTIVES: In 2012 United States Food and Drug Administration (FDA) created a new expedited pathway of 'Breakthrough Therapy Designation' (BTD) to enable early approval of therapies, which have shown substantial activity in early trials. The objective of this study was to understand the impact on BTD on patients and payers. **METHODS:** The data for number of granted BTDs was obtained from FDA.gov. The data for publically disclosed BTDs was obtained from sponsor's press releases. For all products the information for their mechanism of action, type of molecule, trial design, clinical efficacy and safety, and pricing and time to approval (for approved products) were obtained from peer-reviewed publications, conference abstracts, FDA and sponsor websites. **RESULTS:** Since the establishment of the BTD pathway, 37 products have been granted breakthrough therapy designations (2012-2013), of which, 28 have been publically disclosed by the manufacturers and 3 have been approved by the FDA. In terms of indications, 12 (43%) are for cancer, 5 (18%) are for genetic diseases and 4 (14%) are for Hepatitis C Genotype 1. The three approved drugs with BTD are Gazyva, Imbruvica and Sovaldi. The median time to approval for these three drug was ~5 years, significantly shorter than the 2012 median time to approval for priority review applications (6 years). However, the price premium was 30-50% compared to other drugs in the same category. Two of the drugs with BTD did not meet primary endpoint in their pivotal trial. While the BTD pathway promises to reduce development time, the high price is a major concern for payers and patients. **CONCLUSIONS:** BTD is a promising pathway to shorten development time and provides early access, however, high price could pose challenges for payers and patients.

PHP4

4 YOUR KIDS CARE: REDUCING NON-EMERGENT HOSPITALIZATION IN A MEDICAID PEDIATRIC POPULATION THROUGH HANDS-ON TRAINING AND PARENT/CAREGIVER EDUCATION

Grant M, Honeywell A, Dinsmore S, Keleti D, Michael KE, Tan-Torres S, Higgins YL
AmeriHealth Caritas Family of Companies, Philadelphia, PA, USA

OBJECTIVES: As a Medicaid managed care organization (MCO), Keystone First experiences a high volume of pediatric members receiving care for common childhood illnesses at hospital emergency departments (EDs). The 4 Your Kids Care program educates parents/caregivers about what to do when their children get sick, encourages members to engage their primary care physicians, and refers families to appropriate plan resources (e.g., 24/7 Nurse Hotline and Care Management). **METHODS:** A 2.5-hour program educates parents/caregivers about treating common pediatric illnesses at home. The study group (SG) consisted of participating parents/caregivers of 585 pediatric members (≤ 5 years old) in Philadelphia and Delaware counties (Pennsylvania) with at least one prior-year non-emergent ED claim. The matched control group (CG) consisted of 1,189 pediatric members with nonparticipating parents/caregivers in the pre-period and 1,153 in the post-period. The baseline period (January 1, 2010–December 31, 2010) where non-urgent ED claims were collected was followed by the class period (January 1, 2011–September 30, 2011) and one-year follow-up period (October 1, 2011–December 31, 2012). Participants completed a knowledge assessment both before commencement and after completion of the class. **RESULTS:** While the average number of ED visits for non-urgent conditions decreased significantly during the 12-month period in SG ($p < 0.0001$) and CG ($p = 0.0097$), the mean reduction for SG was more than three-fold greater than CG (-46.3% vs. -14.6%, respectively). Amounts paid for ED claims for non-urgent visits during the 12-month period for SG decreased by over twice the amount of CG (-37.8% vs. -17.4%). Questionnaire respondents displayed significant improvements in all six questions regarding knowledge assessment ($p < 0.01$). Participant evaluations of the program were overwhelmingly favorable. **CONCLUSIONS:** 4 Your Kids Care provided effective parent/caregiver education, improved health literacy, and significantly reduced non-emergent pediatric member ED utilization and costs.

PHP5

ROLE OF PATIENT INPUT IN THE CEDAC DRUG REIMBURSEMENT DECISION MAKING PROCESS

Dionne PA, Weicker S, Remple V, Tran T
Pfizer Canada, Kirkland, QC, Canada

BACKGROUND: Since 2010, the Canadian Agency for Drugs and Technologies in Health (CADTH), via the Common Drug Review (CDR), have allowed patient groups to submit issues and outcomes important to them to inform Canadian Expert Drug Advisory Committee (CEDAC) recommendations on drug reimbursement. **OBJECTIVES:** The objectives were to determine if the inclusion of patient input into the CDR process resulted in any change in the CEDAC positive funding recommendation (PFR) rate and to assess potential factors associated with a PFR. **METHODS:** CEDAC recommendations (May 2004 to December 2013) were obtained from the CADTH website. "Efficacy" was defined as occurring when an outcome(s) identified as important to patients achieved statistically significant improvement versus placebo or similar/improved results versus active comparators. Trends in PFR were characterized using descriptive statistics and factors associated with a PFR were assessed using logistic regressions. **RESULTS:** The PFR rate for the 153 recommendations published prior to the patient input process was 54% which was similar to the PFR rate (56%) for the 89 recommendations published after the process was established. A PFR rate of 58% was observed in the 65 submissions that included patient input and 50% in the 24 submissions without. Submissions that showed efficacy in outcomes important to patients had a similar PFR rate (60%) than